Comments on the Draft Tissue TRV Development Approach

Overall process

NOAA feels that a collaborative approach will have the greatest benefit to achieving the desired results in a timely fashion. Beyond helping to refine the TRV selection process, we feel it would be helpful to review the bibliographic database(s) to ensure key studies are included, to be apprised of the studies selected for inclusion in the analyses as soon as practicable, and to review the TRV derivation and the results in a timely fashion.

NOAA has already spent considerable time and effort in a similar effort and has developed appropriate TRVs for juvenile salmonids and PCBs (Meador et al. 2002a). No additional time and effort need be spent on that TRV.

NOAA has also derived appropriate TRVs for TBT for juvenile salmonids and their invertebrate prey (Meador et al. 2002b).

It should be recognized that some substances may not be appropriate for this type of analysis because their tissue concentrations are not related to toxicity, e.g., the non-bioaccumulative metals and, as noted in the draft method, PAHs in fish, which are metabolized.

General Comments on the SSD approach

While we appreciate the value of the proposed comprehensive approach to combing the aquatic life toxicity and concentration data to derive tissue TRVs, we do not feel that such a broad approach is appropriate or necessary for all of the resources and substances of concern. As described below, we feel that a hierarchical approach, using the most species- and taxa-relevant data first, and adding additional information only as-needed is more appropriate.

The 5^{th} percentile (HC5) of the LOER data, not the 10^{th} percentile, should be selected from the best-fitting cumulative distribution function to be consistent with the EPA approach used for AWQC. TRVs developed for use with special status species should be derived as described in this document.

Data selection rules

We feel that rejecting results from all field studies is too restrictive. Studies from sites with a very strong dominance by one substance (or class of substances such as PCBs) and relevant toxicity studies should be considered.

We also believe it is appropriate to calculate tissue residue toxicity metrics from studies with bioaccumulation data and LCp or ECp values. As long as the toxicity and accumulation metrics are time matched, it's just a matter of simple math to determine the tissue concentration associated with the effect. These calculations may help increase the data available for species-specific values. For example, the rainbow trout BCF for a

given toxicant and time point is likely to be relatively constant (this can be checked) as will be the LC50. Simple math gets you the LR50 for trout.

For the relevant studies, select the lowest reported effect concentration that is at the 25th percentile or less, e.g., an EC-25 or EC-10, as comparable to the LOER.

Species/taxa hierarchy:

1st If sufficient papers are available to meet the five-source minimum, select data and develop species-specific TRVs for species needing protection at the individual level (special status species). Also compare the species-specific 5th percentile SSD TRV with the 5th percentile TRV from the SSD derived using all fish species; use the lower number from these two results. Justification for selecting the lower TRV would be that study design and study quality variables can override a species' response. An uncertainty factor would be applied to deal with the use of LOER data instead of NOER data for species to be protected at the individual level.

2nd If less than five appropriate studies are available for the special status species, select the lowest LOER from the available study(ies) and apply a safety factor.

3rd Use all available species data for the non-special status species, treating fish and invertebrates separately, and take the 5th percentiles of the respective best-fitting SSDs for those groups.

4th Combine invertebrate and fish data to estimate the TRVs only when there are no/limited data for that taxa group and the toxicant behavior/mode of action is appropriate.

Endpoint hierarchy

1st If sufficient papers are available to meet the five-source minimum, select only non-lethal endpoints. Include hormesis and quantified behavioral endpoints that are linked to survival, such as predator avoidance and prey capture.

2nd For multiple endpoints for the same study, select only the most sensitive endpoint.

3rd Select studies that used chronic exposures.

4th Never include mortality for PCBs. For other chemicals, include mortality only if other data are insufficient (<5 sublethal studies). If the SSD-derived TRV is driven by the mortality data, use an uncertainty factor on the 5th percentile of the SSD to adjust to a sublethal effect. Also, dividing the LR50 or LOER by 2.27 is not adequate. Such a small number implies a very steep dose-response curve. This may be the case for some toxicants (e.g. metals); however, many exhibit a broad dose-response curve. A factor of 10 would be more appropriate, but we also believe there are more recent papers, e.g., Raimondo et al (2007), that can

provide better information for estimating the appropriate ratios, which will probably be different for the different substances.

5th For multiple-species SSDs, take the geometric mean or median (depending on the distribution of the data) of the same endpoints with multiple values for the same species, but only for studies that had similar exposure concentrations and dosing intervals. Otherwise use the lowest endpoint of all of the studies.

6th Given the paucity of data for some substances, and realizing that some data are better than none, we recognize that some studies may need to be included that are more difficult to relate to data from Portland Harbor. These studies include those that were performed using injection and those based on egg/embryo data. Such studies should be used if no other data can be found and should not be included with the other juvenile/adult data.

7th To avoid large differences in the reported effect concentrations, use data from similar tissues, specifically whole body. The size of the dataset could be increased to include fillet data if there are sufficient data available to convert from a fillet concentration to a whole-body concentration for that chemical and fish species.

8th Preferentially select data from studies that used a range of exposure concentrations, thus better able to calculate the necessary metrics.

Use of data

For population level species, use LOER data and select the 5th percentile as the TRV. The 5th percentile is more consistent with EPA guidance and with the way such an approach is used elsewhere, e.g., in developing AWQC.

The SSD-derived TRVs should include 95% confidence bounds.

The distribution of the data for a TRV should be tested first to decide if an SSD is needed. For some toxicants, the tissue residue data will be normally distributed. For these cases, a mean and variance term may be sufficient. The TRV could be better estimated as the lower 95th CI of the mean, or some agreed percentile.

If the data are lognormal, appropriate algorithms for such an analysis must be used.

For species to be protected on an individual level, use the 5th percentile of the LOER distribution and apply a safety factor. We are still considering what the safety factor should be.

We concur with J. Peterson's observation that TRVs for PAHs can and should be developed for the invertebrates.

We also want to ensure that in the risk characterization the TRV ratios to tissue concentrations would be summed across all measured substances to generate a final risk factor.

References

Meador JP, Collier TK, Stein JE. 2002a. Use of tissue and sediment-based threshold concentrations of polychlorinated biphenyls (PCBs) to protect juvenile salmonids listed under the US Endangered Species Act. *Aquatic Conservation-Marine and Freshwater Ecosystems* 12:493-516.

Meador JP, Collier TK, and Stein JE. 2002b. Determination of a tissue and sediment threshold for tributyltin to protect prey species for juvenile salmonids listed by the U.S. Endangered Species Act. *Aquatic Conservation: Marine and Freshwater Ecosystems* 12: 539-551.

Raimondo S, Montague BJ, Barron MG. 2007. Determinants of variability in acute to chronic toxicity ratios for aquatic invertebrates and fish. *Environ. Toxicol. Chem.* 26:2019-2023.